(d) whether the lack of Epidemiological Intelligence with Government is responsible for the hundreds of deaths in the under-privileged sections of the society?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI A. RAJA) (a) to (d) The National Institute of Communicable Diseases (NICD) carries out the investigations of outbreaks on the request of the State Government and suggest suitable control measures. NICD is also involved in carrying out training of district level health personnel in survillance and control of epidemic prone diseases including detection of early warning signals of outbreaks. During the year 2003, the teams from NICD assisted the State Health Authorities of Andhra Pradesh, Maharashtra, Uttar Pradesh and West Bengal in investigating the outbreaks. For surveillance of disease, the Government of India initiated National Surveillance Programme for Communicable Diseases (NSPCD) in the year 1997 which at present is being implemented in 101 districts of the country. A state based decentralized Integrated Diseases Surveillance Programme (IDSP) is on the anvil to cover all the districts during the 10th plan period.

Cases of Spurious Drugs

532. SHRI K. RAHMAN KHAN: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) the number of cases of adulterated/spurious/fake medicines registered in the country during the current years;

(b) the action taken against the manufacturers of these drugs; and

(c) the steps taken to contain manufacturing of such drugs and the results thereof?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI A. RAJA) (a) As per the feedback available from the Drugs Controllers of States/UTs 129 samples of adulterated/ spurious durgs were detected by them during the period 1-4-2002 to 31-3-2003.

(b) Under the Drugs & Cosmetics Act, 1940 and rules thereunder, the responsibility for regulating manufacture and sale of drugs including taking administrative and legal action against the manufacturers rests with the

Stat Governments. Thus, based on the gravity of the offence detected, necessary punitive action under the said Act and Rules is initiated by the concerned State Drugs Controllers.

(c) The State Governments are advised from time to time to gear up their enforcement machinery to detect and unearth spurious/fake drugs as well as to provide and strengthen their regulatory infrastructure; to establish State level testing labs, to ensure speedy analysis of drug samples for which they are provided assistance to strengthen and augment infrastructure facilities in such lab. The State Governments have also been advised to keep strict surveillance over the suspected dealers; collection of survey samples under National Survey Quality Evaluation of Drugs (NSQED) programme; constitution/reactivation of State Drug Advisory Committees in which various trade and industry association as well as consumer associations can file representations establishment of separate intelligence-cum-legal cell; to develop efficient communication facilities and recall procedures; engaging experience counsels for fighting spurious drug cases etc.

Government of India has taken the following initiatives to tackle the problem of spurious drugs:-

(i) Detailed guidelines in respect of strategies required to be adopted for efficient surveillance over the movement of spurious drugs were Conveyed to the States Governments November 17. 1999 to ensure focused surveillance over manufacture and sale of spurious durgs.

(ii) Issue concerning alleged sale of spurious drugs was taken up by the Union Health Minister with State Health Ministers in the 7th Conference of Central Council of Health and Family Welfare (CCH&FW) held on 12-13 July, 2001. CCHFW resolved that in order to address issue relating to the increasing reports of spurious drugs/counterfeit drugs, special attention requires to be given to monitor and unearth such illegal activities by constituting a separate intelligence-cum-legal cell in the respective drug control organization and in seeking cooperation of the pharma industry, trade as well as the police.

(iii) Department of Health constituted a broad based Committee under the Chairmanship of DGHS in July, 2001 to examine issues

concerning the problem of spurious drugs. The observations and recommendations of this Committee have been circulated on September 16, 2002 to all State Drugs Controllers for their information and necessary action in the matter.

(iv) Union Minister of Health and Family Welfare wrote to all Chief Ministers on October 8, 2002 on the issue of spurious durgs, seeking their personal intervention to ensure that adequate measures are taken in each State to vigorously pursue the strategies needed to preclude any possibility of menace of spurious products so as to collectively ensure its total eradication.

(v) A meeting of Health Ministers and Senior Officials of 13 major States of the country was convened by Union Minister of Health and Family Welfare on 12-11-2002 to ensure concerted action to check any possible movement of spurious drugs in the country and to involve all stake holders to fight this menace. Suggestions/ views which emerged out of discussion were forwarded on January 8, 2003 to all the State Governments for their information and necessary action.

(vi) In order to increase the number of drug samples tested in the country and to bring down the reporting time to less than a month as against 3 to 6 months presently being taken by many laboratories, a comprehensive plan has been undertaken by Central Government to strengthen State Drug Laboratories under a Capacity Building Project with World Bank assistance.

(vii) In order to ensure speedy information exchange and networking of all States and Central Drugs Control Offices and Laboratories, computerization project has been undertaken by Central Government.

(viii) A specialized training programme for drugs control officers of all Sate Governments responsible for keeping surveillance over possible movement of spurious drugs has been formulated and was conducted from 24-27 June, 2003 by the Central Government in cooperation with FDA, Maharashtra at Mumbai. 26 drugs control officers from different States had attended the training programme at FDA, Mumbai.

(ix) Government of India have constituted a Committee of experts on January 27, 2003 under the Chairmanship of Dr. R.A. Mashelkar, Director General, Council for Scientific and Industrial Research (CSIR) to undertake a comprehensive review of the drugs regulatory system in the country including the problem of spurious and substandard drugs and recommend remedial measures to deal with this problem effectively. The Government has initiated steps to study the measures recommended in the report recently submitted by the expert committee.

Mashelkar Committee Report on Spurious Drugs

533. SHRI RAMA MUNI REDDY SIRIGIREDDY: Will the Minister of HEALTH AND FAMILY WELFARE be pleased to state:

(a) whether it is a fact that Mashelkar Committee set up to look into spurious drugs has submitted its report;

(b) if so, the recommendations made by the Committee;

(c) whether Government would bring a comprehensive Bill before the House to amend the Drugs and Cosmetic Act;

(d) if so, the details thereof;

(e) if not, the reasons therefor; and

(f) the steps Government have taken/proposed to take to upgrade the Central Drug Standard Control Organisation to the level of the Central Drug Administration?

THE MINISTER OF STATE IN THE MINISTRY OF HEALTH AND FAMILY WELFARE (SHRI A. RAJA) (a) to (f) The Expert Committee headed by Dr. R.A. Mashelkar has submitted its report to Government in two parts. An interim report was submitted in August 2003, dealing with penalties for various offences under the Drugs and Cosmetics Act, 1940. A summary of the recommendations contained in the interim report is given in the Statement *(See* below*)*.

Government has initiated steps to bring forth a legislation for amending the Drugs and Cosmetics Act on the suggested by the committee.

The committee has submitted the final report to the Government in November, 2003. Government has initiated steps to examine the report